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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,554	11/12/2003	Thomas A. Burba	ESI	6899
21270	7590	06/18/2007	EXAMINER	
HUGH D JAEGER, P.A. P.O. BOX 672 WAYZATA, MN 55391-0672			JA WORSKI, FRANCIS J	
ART UNIT		PAPER NUMBER		
3768				
MAIL DATE		DELIVERY MODE		
06/18/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,554	BURBA ET AL.	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 - 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 29 - 50 and 57 - 66 is/are allowed.
- 6) Claim(s) 1 - 28, 51 - 56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 - 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim introduces '—at least one guide surface/external vent' whereas later back-references assume these terms to be plural, see for example claim 3 lines 13 – 14 and claims 5 - 6 as exemplary.

Dependent claims variously inherit the defect.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Strauss (US4907595) insofar as Strauss teaches an ultrasound doppler probe positioning air immersion shell system for the human eye which comprises:

Upper cylindrical body 8 having a through passage 4 which vents pressure source P via its tube portion, lower cylindrical body 2 and a fluid (air) transfer port in the outflow opening of 4, and whereby a lip 7 extends over 'the outer orbital border or its neighboring parts' which is interpreted to mean extending at least over the cornea and portions of the sclera during the ophthalmologic measurement procedure.

Claim 2 is further rejected and also claims 51 – 52 , 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Driller et al (US4484569) which teaches an ultrasound diagnostic and therapeutic probe positioning system for the human eye of closed end or component immersion type, comprising an upper cylindrical body 76 together with or alternatively only the cylindrical portion of 128 or the cylindrical portion of its Fig. 5 counterpart 160, a lower cylindrical portion 120, a vent 176 of Fig. 5 in the upper cylindrical body as so defined, and a fluid transfer port which is the ingress opening of vent 76 or the forward opening of 120 just ahead of transducer 122. The probe of Driller et al by virtue of being enclosed by membrane 130 is capable of placement extending over the sclera, there being no further adaptation particularizations claimed.

With respect to claims 51 – 52 and 54 a different anticipatory reading applies, using latitude in defining upper and lower: the immersion system includes upper transducer chamber 76 and lower chamber 160 having the internal bore of 120 and/or the inner bore of portion 76 as a guide means which permits transducer 122 to protrude into the lower chamber, vent means in the form of the aperture of 120 which permits

fluid communication between the so-defined upper and lower chambers, fluid transfer port communicating via 160 with the upper chamber, and a peripheral lip in the region of 132 of the lower chamber is coaxially oriented with respect to the transducer and is adapted for contacting the eye via membrane layer 130.

Claim 2 is further rejected under 35 U.S.C. 102(b) as being anticipated by Carlin (US3771660) which teaches an ultrasound probe positioning liquid immersion shell system comprising an 'upper' cylindrical body 7 and a 'lower' body 5 having a cylindrical portion, a vent 21 in the upper cylindrical body for draining fluid from the reservoir or from the immersion shell system, and a fluid transfer port 22, whereby lip 6 extends over and about the human eye with extension out onto the sclera and beyond, to the periorbital region.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Parra (US5137029) insofar as Fig. 11 shows an ultrasound immersion shell system for the human eye comprising an upper cylindrical portion of eyecup 84, lower cylindrical portion cover 82 and medicament container, a plurality of external vents 90, 91 with guide surface channels extending from the top to bottom surface of the eyecup and capable of serving as guide means to sight-align with holes 88, 89 in medicament reservoir cover 82 which serve also as fluid transfer ports. Lip 85 is capable of extending over the scleral region of the eye.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Driller et al. If in the alternative, Driller et al be argued to fall short of anticipation insofar as being a closed system does not suffice to literally anticipate a scleral overlay device, then since this inventive group was known to apply therapies to the sclera, see patent face fig. Col. 2 top, then it would have been obvious with the current construct to extend onto the sclera in order to treat it since the diagnostic and treatment transducers are confocal.

Claim 1 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Parra as interpreted above, further in view of Silver (US3945381). It would have been obvious in view of Silver 38 to provide vents which are overall external to the upper cylindrical (eyecup) portion in order to not apply excess pressure to the eye to which the ophthalmic solution is being applied.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Driller et al as applied to claim 51 above, and further in view of Henriksen et al (US4930512) since the latter evidences that it would have been obvious to spring-load a transducer guide such as in Driller et al into forward engagement via spring 50 so that for example the standoff distance in the latter is fixed..

Claims 55 – 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driller et al as applied to claim 51 above, and further in view of Coleman et al (US6315727) since the latter teaches (see claim 24) that an eyepiece for an investigative ultrasound probe may be made integral and of polymers, the latter being understood to include opaque materials with respect to medical applicators.

Allowable Subject Matter

Claim 29 – 50, 57 – 66 are allowed.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski
Primary Examiner